

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

<b>IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION</b>	<b>MDL No. 2875</b>  <b>HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	

**MEMORANDUM OF LAW IN RESPONSE TO DEFENDANT TORRENT'S  
SPECIFIC MOTIONS *IN LIMINE* FOR THE TPP TRIAL**

**TABLE OF CONTENTS**

ARGUMENT.....1

I. The Meridan Report is Admissible.....1

II. “Cheaper Chinese API” Email is Relevant and Should be Admitted .....5

II. Financially Motivated.....7

III. Recalled in 2018.....10

IV. Jenny Yang’s Email is Admissible .....12

Conclusion.....14

## TABLE OF AUTHORITIES

<b>Cases</b>	<b>Page(s)</b>
Bosley v. DePuy Synthes Sales Inc. (W.D. Wash. Oct. 4, 2023).....	10
Copeland v. Metro. Atlanta Rapid Transit Auth., 2011 WL 13174559m at *3 (N.D. Ga., May 3, 2011).....	3
Erickson v. Biogen, Inc., 2019 WL 2525424, at *3 (W.D. Wash. June 19, 2019) .....	3
Forrest v. Parry, 930 F.3d 93, 114–15 (3d Cir. 2019) .....	2
Godelia v. Zoll Servs. ....	4
LLC, 2019 WL 3883682, at *2 (S.D. Fl. Aug. 16, 2019)	
Krys v. Aaron, 2015 WL 3857085, at *3 (D.N.J., June 22, 2015) .....	3
Lexington Ins. Co. v. W. Pennsylvania Hosp., 423 F.3d 318, 328 (3d Cir. 2005) .....	8
McQueeney v. Wilmington Trust Co. 779 F.2d 916, 928 (3d Cir.1985) .....	8
Novick v. Shipcom Wireless, Inc., 946 F.3d 735, 739–40 (5th Cir. 2020) .....	4
Odate v. AHRC Health Care, Inc., 2023 WL 8648167, at *11 (S.D.N.Y. Dec. 14, 2023) .....	4
Sabre Int’l Sec. v. Torres Advanced Enter. Sols., LLC, 72 F.Supp.3d 131, 144 (D.D.C. 2014) .....	3
Scully v. Wackenhut Corp., CIV. 10-4633 RMB/AMD, 2013 WL 3168655.....	8
United States ex rel. Jordan v. Northrop Grumman Corp., 2003 27366250, at *3 (C.D. Cal. Mar. 10, 2003) .....	4
<b>Other Authorities</b>	
Federal Rules of Evidence 407.....	4

## **ARGUMENT**

### **I. THE MERIDAN REPORT IS ADMISSIBLE**

Torrent's request to exclude the audit report issued by Meridan Consulting, LLC (the "Meridan Report") entirely disregards the document's scope and purpose. (See Torrent Ex. 1, TORRENT-MDL2875-00433346.) While Torrent misconstrues the Meridan Report as a post-recall investigation covering products other than valsartan, it is, in fact a *sitewide* audit of the practices and procedures in effect at the Indrad facility that manufactured VCDs encompassing the period VCDs were manufactured there. (Torrent Ex. 1, at 4.) It specifically examined the

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. (Torrent Ex. 1, at 19; Pl. Ex. 1, June 6, 2021 Jaiswal Dep., at 761:17–764:3, 764:13–19.) The findings in the Meridan Report were not product-specific, but rather, were wide-ranging as to the implementation of procedures across various product lines, [REDACTED]

[REDACTED] (Torrent Ex. 1, at 4.) [REDACTED]

[REDACTED]. (Pl. Ex. 2, June 4, 2021 Jaiswal Dep., at 266:20–23, 268:5–18, 269:16–270:12, 272:21–275:17, 279:12–15; Pl. Ex. 3, TORRENT-MDL2875-

00208351.) In the context of the Meridan Report as a sitewide policy and procedure audit covering the period that Torrent manufactured VCDs, Torrent’s criticisms fall flat.

The Meridan Report is relevant regardless of whether it specifically references VCDs. Evidence is “only irrelevant if it bears on no aspect of the overarching theory” and “[t]o that effect, evidence is not irrelevant merely because it does not show causation ... or does not focus on the particular activities” at issue in the case. *Forrest v. Parry*, 930 F.3d 93, 114–15 (3d Cir. 2019). The Meridan Report directly corresponds to the TPP Plaintiffs’ overarching theories involving cGMP noncompliance as it demonstrates that the procedures *applicable to VCDs* were not followed.<sup>1</sup> Further to the point, [REDACTED]

[REDACTED]. (Pl. Ex. 2, at 266:20–23, 268:5–18, 269:16–270:12, 272:21–275:17, 279:12–15.) The Meridan Report demonstrates a relevant pattern and practice of noncompliance with standard

---

<sup>1</sup> Among the procedures examined were: [REDACTED]

[REDACTED]. (Torrent Ex. 1, at 19; Pl. Ex. 1, 761:17–764:3, 764:13–19.)

operating procedures at the facility that manufactured the at-issue VCDs, including those that relate to OOS and NDMA.

Torrent has also failed to establish a risk of prejudice, confusion, or waste of time. Indeed, Torrent’s Rule 403 argument largely rehashes its relevance argument, pointing to the existence of an “unrelated” document as the basis for prejudice and confusion. (Torrent MIL 1, at 3.) As described above, the Meridan Report is directly related to VCD issues in this case. Moreover, the authorities upon which Torrent relies for its argument that the Meridan Report is “confusing,” excluded audits because they related to claims that were dismissed or never raised. *See, e.g., Krys v. Aaron*, 2015 WL 3857085, at \*3 (D.N.J., June 22, 2015).<sup>2</sup> By contrast, the Meridan Report is highly probative of the claims Plaintiffs are pursuing at trial involving the value of Torrent’s adulterated drugs, including that the Indrad facility where Torrent manufactured its VCDs in a state of noncompliance with its own procedures.

Finally, Torrent argues that the Meridan Report constitutes evidence of subsequent remedial measures. (Torrent MIL No. 1, at 4.) However, the purpose of

---

<sup>2</sup> The remaining cases cited by Torrent are likewise inapposite. *See Copeland v. Metro. Atlanta Rapid Transit Auth.*, 2011 WL 13174559m at \*3 (N.D. Ga., May 3, 2011) (excluding police internal investigation evidence because it related only to an “instance of FMLA leave about which Plaintiff has not complained.”); *Sabre Int’l Sec. v. Torres Advanced Enter. Sols., LLC*, 72 F.Supp.3d 131, 144 (D.D.C. 2014) (allowing introduction of one audit while excluding evidence of another); *Erickson v. Biogen, Inc.*, 2019 WL 2525424, at \*3 (W.D. Wash. June 19, 2019) (holding nationwide internal investigation data was irrelevant absent allegation of *pattern or practice*).

the Meridan Report was to document the conditions at the Torrent Indrad facility.

(See Torrent Ex. 1, at 2 [REDACTED])

[REDACTED].) Meridan characterized its own report as [REDACTED] (*Id.*

at 16.) The Meridan Report contains no evidence of remedial measures but, to the

contrary, merely describes the policies, procedures, and practices that were in effect

at the Indrad facility for the five years prior to the issuance of the Report. (*Id.* at 4.)

Accordingly, the Meridan Report is outside the scope of Fed. R. 407<sup>3</sup> An audit,

which does not make the “earlier injury or harm less likely to occur” is not subject

to exclusion under Fed. R. Evid. 407. *Novick v. Shipcom Wireless, Inc.*, 946 F.3d

735, 739–40 (5th Cir. 2020) (quoting Fed. R. Evid. 407). Federal courts across the

country regularly reject arguments like Torrent’s and admit similar reports.<sup>4</sup> The

---

<sup>3</sup> Even if the Meridan Report was within the scope of Rule 407, it would be subject to an exception. Rule 407 contemplates admission of post-incident evidence to show feasibility. Fed. R. Evid. 407 1972 Advisory Committee Notes (“Other purposes are, however, allowable, including ownership or control, existence of duty, and feasibility of precautionary measures, if controverted.”).

<sup>4</sup> “[A] defendant’s internal investigations and reviews might constitute the initial step toward identifying the need for particular remedial action, but they are not themselves excluded under Rule 407... It is only if changes are implemented as a result of the tests that the goal of added safety is furthered; and, even then, it is only evidence of those changes that is precluded by the rule.” *Oate v. AHRC Health Care, Inc.*, 2023 WL 8648167, at \*11 (S.D.N.Y. Dec. 14, 2023)(quotations omitted) (holding that potential corrective improvements recommended by auditor were outside the scope of Rule 407 and so were admissible); *see also Godelia v. Zoll Servs., LLC*, 2019 WL 3883682, at \*2 (S.D. Fl. Aug. 16, 2019) (finding audit report was not a subsequent remedial measure); *United States ex rel. Jordan v. Northrop Grumman Corp.*, 2003 27366250, at \*3 (C.D. Cal. Mar. 10, 2003) (declining to exclude audit under Rule 407).

Meridan Report is not evidence of changes to Torrent's practice or procedures *after* VCDs were manufactured but rather documents deficiencies in those procedures *while* VCDs were manufactured. (See Torrent Ex. 1, at 4.) The Meridan Report is therefore admissible.

## **II. "CHEAPER CHINESE API" EMAIL IS RELEVANT AND SHOULD BE ADMITTED**

The Court should deny Defendant's motion to exclude the email sent by Torrent employee, Kelly Gegenheimer which states that Torrent is [REDACTED] [REDACTED] (Pl. Ex. 4, TORRENT-MDL2875-00005763). The language in that email sent in the ordinary course shows what Torrent's employees thought in real time, and also illustrates the elevation of profit over safety, a central theme in this trial. The cases Defendants cite on this issue are irrelevant and non-persuasive.<sup>5</sup> Additionally, Defendants once again fail to provide context for this email and subsequent questioning, and incorrectly accuse Plaintiff of "deliberately," "routinely and intentionally misquot[ing]"<sup>6</sup> this email by using the word cheap instead of cheaper.

---

<sup>5</sup> All of the cases cited by Defendants simply reiterate the concepts of excluding evidence under 403, and none of them found it was improper to add or remove a comparative suffix from a word used by a party.

<sup>6</sup> Torrent MIL No. 2.



Plaintiff questioned multiple witnesses about this document, including Dawn Chitty and Sushil Jaiswal. Each witness had the opportunity to correct any misstatements or inaccurate readings of the email, which did not occur - and Torrent fails to demonstrate to the contrary. This email is absolutely relevant to explain why Torrent selected ZHP as its API manufacturer for VCDs in the first place, and ties in with ZHP's admission to the FDA investigator that the ability to more cheaply manufacture the valsartan API with the zinc chloride process is what allowed ZHP to dominate the world market share for the drug.

Factually, ZHP's valsartan API was indeed cheap, cheaper, and to Plaintiffs' understanding, the cheapest option. Stated differently, it's not just that ZHP's API was slightly cheaper than the competition; [REDACTED]  
[REDACTED].<sup>7</sup> Further, ZHP was Torrent's only API supplier.<sup>8</sup> The characterization of the email in the questioning was at all times reasonable, and the witness and counsel had every opportunity to clarify if they thought that was necessary. This evidence, taken as a whole, supports Plaintiffs' position that Torrent was more concerned with the cost of the API than the quality. The context is even more apparent when the email is considered with documents

---

<sup>7</sup> Pl. Ex. 7, TORRENT-MDL2875-00436416.

<sup>8</sup> Pl. Ex. 2, at 148:23-149:2. Torrent only had on API supplier, [REDACTED]  
[REDACTED]

Pl. Ex. 5, at 72:3-10.)

such as the email from Jenny Yang,<sup>9</sup> which described significant concerns about ZHP's practices and adequacy as an API manufacturer (*see* Pl.'s Response to Torrent's MIL No. 5).<sup>10</sup> Despite these troubling warnings, Torrent continued to use ZHP as its API supplier and continued to blindly rely on them for critical information, because Torrent did not want to move on from an API supplier with such low costs. Defendant can explain the email at trial. The motion should be denied.

### **III. FINANCIALLY MOTIVATED**

Defendants request to exclude the July 5<sup>th</sup> and 18<sup>th</sup> emails should be denied. Plaintiff will demonstrate that Torrent's actions were driven by a fear of losing profits, and Defendant's assertion that only two documents support Plaintiffs' position is a massive understatement. In fact, Torrent's prioritization of profits is a theme that runs throughout this case and is illustrated in a number of documents.<sup>11</sup>

Torrent curiously raises issues as to foundation. Authenticity cannot be reasonably disputed, and the Court has already cautioned the parties that it expects authentication to be agreed to. (Fed. R. Evid. 901). "The burden of proof for

---

<sup>9</sup> Torrent's auditor of ZHP's facilities.

<sup>10</sup> Pl. Ex. 10, TORRENT-MDL2875-00124209.

<sup>11</sup> Even other documents that are the subject of Defendant's motion pertain to Torrent's prioritization of profits. *See* Pl. Ex. 4, TORRENT-MDL2875-00005763 (Cheaper Chinese API); Pl. Ex. 7, TORRENT-MDL2875-00436416 (API with 60% price reduction).

authentication is slight.” *Lexington Ins. Co. v. W. Pennsylvania Hosp.*, 423 F.3d 318, 328 (3d Cir. 2005) (citing *McQueeney v. Wilmington Trust Co.*, 779 F.2d 916, 928 (3d Cir.1985)). All that is required is a finding that the item is what the proponent claims it is. (Fed. R. Evidence 901). It is not required that a document be introduced through its author. *Lexington Ins. Co. v. W. Pennsylvania Hosp.*, 423 F.3d 318 (3d Cir. 2005) (holding that a document was authentic even without identifying the author or date created as the document was produced by the party the document was proffered against); *Scull v. Wackenhut Corp.*, CIV. 10-4633 RMB/AMD, 2013 WL 3168655, at \*1 (D.N.J. June 20, 2013) (“Neither Federal Rule of Evidence 901 nor applicable caselaw imposes a requirement that a document be authenticated only by its author”).

Torrent’s argument that these documents should be excluded under 901 is nonsensical. Torrent provided both documents at issue to Plaintiff, with a Torrent bates-stamp that is specific to this MDL, and both documents contain communications sent to and from Torrent employees via their Torrent email addresses. Specifically, the July 5<sup>th</sup>, 2018 email was authored by a ZHP employee and sent to Torrent employee, Dhrumit Shah.<sup>12</sup> Mr. Shah received the July 5<sup>th</sup> email to his Torrent email address, and then forwarded the email to the rest of Torrent’s quality team (over twenty additional people) via their TorrentPharma.com email

---

<sup>12</sup> Pl. Ex. 6, TORRENT-MDL2875-00090454.

addresses. Mr. Shah himself was asked about this document in his deposition; he confirmed he read it and forwarded it to the technical team.<sup>13</sup>

The July 18<sup>th</sup>, 2018 email was sent by Arunesh Verma<sup>14</sup>, the Chief Operating Officer for the United States based Torrent company at the time, from his Torrentpharma.us email address and sent to six Torrent employees at their respective Torrent email addresses.<sup>15</sup> Multiple witnesses, including Dawn Chitty<sup>16</sup> and Sushil Jaiswal,<sup>17</sup> were asked about this document, confirmed they were familiar with the document and remember receiving it. Therefore, discussion of Torrent's financial motivation during its nitrosamine investigation, including via these documents, is admissible,<sup>18</sup> and the Defendant's motion should be denied.

#### **IV. RECALLED IN 2018**

Defendants request that this Court exclude any argument Torrent should have recalled its VCDs on June 20, 2018. In support of their position, Defendants cite to

---

<sup>13</sup> Pl. Ex. 8, Dhruvit Shah Dep. Tr., at 336:6–13.

<sup>14</sup> Torrent's summary of Mr. Verma's "desires" when sending this email is completely fabricated, total speculation, and not based in any evidence in the record. Further, it is inaccurate. Defendants allege Mr. Verma wanted to "put an end to the uncertainty" and "rule out quickly" whether Torrent's valsartan contained NDMA, however, Torrent was able to get its VCDs released from quarantine that very day without having "ruled out" anything, as Torrent still had no idea whether its VCDs were contaminated or not.

<sup>15</sup> Pl. Ex. 9, TORRENT-MDL2875-00005188.

<sup>16</sup> Pl. Ex. 5, at 244:8–246:2.

<sup>17</sup> Pl. Ex. 2, at 257:9–258:16.

<sup>18</sup> It is Plaintiffs' position that discussion that Torrent was financially motivated is admissible even if these two emails were excluded.

*Bosley v. DePuy Synthes Sales Inc.* (W.D. Wash. Oct. 4, 2023) and contend this case stands for the exclusion “of evidence of a delayed recall because it would be highly prejudicial and would depict the defendant as a bad corporate actor.” Once again, this is misleading. The cited language is nowhere to be found in this order. In the order, the Court issued rulings on numerous issues raised at the motion in limine stage, and in response to Defendant’s request to exclude information pertaining to a recall, the Court simply stated, “Defendants’ Motion in Limine No. 6: “All Evidence and Argument Concerning a Failure to Recall” is GRANTED.” There is no information as to why the Court ruled this way.

Defendants also cite to the underlying motion filed by Defendants in *Bosely*; however, this does not provide any clarity on why the motion was granted. Several arguments were made to exclude this evidence; most notable however, is the argument that “such argument or evidence is irrelevant as **Plaintiff has not pled any allegations, procured any testimony or evidence, and has not had any expert opine** that the ATTUNE® should have been recalled.” The fact that no evidence was put forward on this issue could very well have been (and from a commonsense perspective, likely was) what prompted the Court to exclude this evidence, not because evidence of a delayed recall is highly prejudicial. The cited case does not stand for what Defendants assert it does, and it is disingenuous and improper for Defendants to try to sneak in their own reasoning to a Court’s ruling.

The fact is that Torrent should have continued to keep its VCDs in quarantine until it could demonstrate nitrosamines were not present in the medication, as well as be forthcoming with customers during this time about the status of the investigation into the nitrosamine contamination<sup>19</sup> (*See* Pl.’s Mot. for Partial Summ. J. Against Torrent). Plaintiff is not waiving any other argument or evidence pertaining to this issue, and is not waiving the argument that a recall should have been implemented earlier than it was.

#### **V. JENNY YANG’S EMAIL IS ADMISSIBLE**

The Court should deny Defendant’s motion to exclude Jenny Yang’s email as it is highly relevant. This email relays the impressions of Torrent’s auditor after he audited ZHP’s facility back in 2015, not long after Torrent started selling its VCDs in the United States.<sup>20</sup> In the email, Jenny tells Torrent employees that: [REDACTED]

[REDACTED]

---

<sup>19</sup> Defendants include a timeline of events in their MIL, but exclude a couple of key dates that put support Plaintiffs’ position that Torrent should have kept the VCDs in quarantine until they could confirm nitrosamines were not present and communicated candidly with customers about the status of the investigation:

- July 6, 2018: Torrent learns its valsartan with ZHP’s API is recalled in Europe;

• [REDACTED]

[REDACTED]

<sup>20</sup> Pl. Ex. 10, TORRENT-MDL2875-00124209.

[REDACTED]

[REDACTED]

These findings are significant and concerning, as these are systemic cGMP violations. Further, they are relevant to demonstrate that Torrent had good reason not to blindly trust ZHP. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. Armed with this information provided by Yang, Torrent, at a minimum, needed to take additional steps to insure information provided by ZHP was accurate (such as independently verifying these genotoxicity statements), or start looking for a new API supplier.

Defendant's argument that "to matter under cGMPs, Dr. Yang's concerns would have had to be formalized in an audit report" again twists and misstates the evidence in this case, and is a non-sensical position. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED] He does not say that an email raising significant concerns about an API supplier is not worth responding to or does not need to be followed up on;

---

<sup>21</sup> Pl. Ex. 11, Philip Russ Dep. Tr., at 305:9–12.

<sup>22</sup> *Id.* at 305:12–15.

just that the proper mechanism for doing so is through the corrective and preventative action (CAPA) process.

Interestingly, Defendants ask Plaintiffs to do the impossible by providing evidence that Torrent “did nothing to follow up with Dr. Yang’s concerns.”<sup>23</sup> It is for Torrent to explain what it did. The fact that no evidence has been found suggesting proper action was taken is quite telling. If Defendants disagree, they can present such evidence at trial.<sup>24</sup>

### CONCLUSION

For the reasons stated above, Plaintiffs request that the Court deny all of Defendant’s *motions in limine*.

Dated: February 26, 2024

Respectfully submitted,

/s/ Ruben Honik

Ruben Honik

**HONIK LLC**

1515 Market Street, Suite 1100

Philadelphia, PA 19102

Phone: (267) 435-1300

[ruben@honiklaw.com](mailto:ruben@honiklaw.com)

/s/ Daniel Nigh

Daniel Nigh

**NIGH, GOLDBERG, RASO, &  
VAUGHN, PLLC**

14 Ridge Square NW, 3<sup>rd</sup> Floor

Washington, DC 200016

Phone: (202) 792-7979

[dnigh@nighgoldenberg.com](mailto:dnigh@nighgoldenberg.com)

---

<sup>23</sup> Torrent MIL No. 5.

<sup>24</sup> Notably, Defendants did not move on this issue when they filed Daubert motions seeking to limit or exclude Russ’ testimony, and they could have.



/s/ Adam Slater

Adam Slater

**MAZIE, SLATER, KATZ &  
FREEMAN, LLC**

103 Eisenhower Pkwy, 2nd Flr.

Roseland, NJ 07068

Phone: (973) 228-9898

[aslater@mazieslater.com](mailto:aslater@mazieslater.com)

/s/ Conlee S. Whiteley

Conlee S. Whiteley

**KANNER & WHITELEY, LLC**

701 Camp Street

New Orleans, LA 70130

Phone: (504)-524-5777

[c.whiteley@kanner-law.com](mailto:c.whiteley@kanner-law.com)

***MDL Plaintiffs' Co-Lead Counsel***

/s/ Jorge Mestre

Jorge Mestre

**RIVERO MESTRE LLP**

2525 Ponce de Leon Blvd., Suite 1000

Miami, FL 33134

Phone (305) 445-2500

[jmestre@riveromestre.com](mailto:jmestre@riveromestre.com)

/s/ Gregory P. Hansel

Gregory P. Hansel

**PRETI, FLAHERTY, BELIVEAU &  
PACHIOS, CHARTERED, LLP**

One City Center

P.O. Box 9546

Portland, ME 04112

Phone: (207) 791-3000

[ghansel@preti.com](mailto:ghansel@preti.com)

***Third-Party Payor Economic  
Loss Co-Lead Class Counsel***